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1652

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

OMURA et al.

Appln. No. 09/914,286

Filed: August 24, 2001

FOR: AVERMECTIN AGLYCON SYNTHASE GENES

Confirmation No.: 2354

Atty. Ref.: 468-30

Group Art Unit: 1652

Examiner: N.T. Nashed

* * *

SUPPLEMENTAL RESPONSE

Monday, February 9, 2004

U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

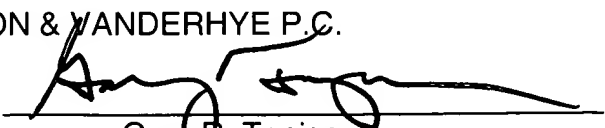
Sir:

Further to the Amendment filed February 6, 2004, consideration of the attached two cases and the following remarks is respectfully requested. It is well established that an assertedly anticipatory reference must satisfy the written description and enablement requirements of Section 112. See *PPG Industries, Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one to skilled in the art to make the anticipating subject matter."). This was recently cited with approval in *Elan Pharm. Inc. v. Mayo Foundation*, 68 USPQ2d 1373 (Fed. Cir. 2003). The claims require particular sequences which are absent in the references cited in the Office Action. Applicants submit that the cited references fail to satisfy the Section 112 requirements for the claimed invention. Please contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYTE P.C.

By:


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Reg. No. 43,180

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Cir. 1988) (*en banc*), *cert. denied*, 490 U.S. 1067 (1989).

The ALJ had criticized Modine's choice of the data that were included in the grandparent application as filed, for Modine had replaced a graph of computer-generated heat transfer data, that appeared in an early draft of the patent application, with later-obtained data and comparison with a different prior art condenser. Modine explained at trial the flaws in the first set of data, and the reasons for the change to data that were believed to be more accurate and to present a more useful comparison. Although there was no challenge at trial to either the correctness or the veracity of this explanation, the ALJ nonetheless found that Modine intended to deceive the patent examiner. The ALJ also criticized Modine's description of the prior art and the arguments presented to the examiner concerning the prior art.

The Commission found that comparative data with Modine's most efficient prior condenser were included in graphs in the patent application, and that certain computer-generated early data were replaced with more accurate data. Substantial evidence supports the Commission's findings that there was neither material withholding nor intent to deceive in Modine's selection of data and in the prosecution of the patent application. We remark that the rule of *Kingsdown* evolved in response to the "plague" of collateral attacks, of which this is an example, wherein routine patent practice is challenged without substance. See *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939, 15 USPQ2d 1321, 1327 (Fed. Cir. 1990).

The holding that there was not inequitable conduct is affirmed.

Summary

Having interpreted the claims *de novo*, we vacate the Commission's rulings on the issues of infringement, and remand for findings and redetermination with respect to literal infringement and infringement under the doctrine of equivalents. In all other respects the Commission's decision is affirmed.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED.

Mayer, J., dissents.

U.S. Court of Appeals Federal Circuit

PPG Industries Inc. v. Guardian Industries Corp.

No. 95-1222

Decided February 6, 1996

PATENTS

1. Infringement — Literal infringement (§120.05)

Defendant's automotive glass infringes claims of patent for solar control glass, since accused glass satisfies all limitations of asserted independent and dependent claims, including level of ultraviolet transmittance no greater than 31 percent; inventors' miscalculation of ultraviolet transmittance level of claimed glass due to software error does not warrant contrary conclusion, even though ultraviolet transmittance of accused glass would appear to be above 31 percent if tested with inventors' inaccurate equipment, since asserted claims cover glass that transmits no more than 31 percent of sun's ultraviolet radiation, rather than glass that is measured at no more than 31 percent ultraviolet transmittance using flawed testing system.

2. Patentability/Validity — Specification — Claim adequacy (§115.1109)

Claims for solar control glass are not invalid for indefiniteness under 35 USC 112, even though inventors miscalculated ultraviolet transmittance level of claimed glass due to software error, since claims are precise in quantifying essential ingredients and transmittance tolerances of claimed compositions and give clear notice of what compositions fall within their range, since inventors thus distinctly claimed subject matter that they regarded as their invention despite misconception as to ultraviolet transmittance levels, and since inventors' failure to specify method to be used in testing ultraviolet transmittance does not render claims invalid.

3. Patentability/Validity — Specification — Enablement (§115.1105)

Specification of patent for solar control glass satisfies enablement requirement of 35 USC 112, even though inventors' miscalculation of ultraviolet transmittance level of claimed glass could lead careful reader of specification to conclude that glass with iron content and "redox" ratio of accused glass would not be likely to satisfy ultraviolet transmittance limitation of asserted claims, since embodiment of patent having same

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appeals
suit
Guardian Industries

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6, 1996

ral infringement

glass infringes
control glass, since
limitations of as-
pendent claims,
et transmittance
t; inventors' mis-
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tware error does
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— Specification
15.1109)

ass are not inval-
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— Specification
(105)

or solar control
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ttance level of
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t glass with iron
f accused glass
isfy ultraviolet
asserted claims,
it having same

composition and transmittance properties as
accused glass could be made by person of
ordinary skill in art without "undue experi-
mentation" in view of specification's provi-
sion of guidance in selecting operating pa-
rameters that would yield claimed result.

4. Patentability/Validity — Anticipation — Identity of elements (§115.0704)

Patentability/Validity — Obviousness — Relevant prior art — Particular inven- tions (§115.0903.03)

Infringement plaintiff is likely to prevail
on issues of whether patent for "solar control
glass" is anticipated or rendered obvious by
prior Russian patent, since composition of
prior patent contains significant amounts of
rare earth elements that absorb ultraviolet
radiation and visible light, and thus does not
meet limitations of claimed glass, and since
defendant has not rebutted showing that
Russian patent teaches away from composi-
tions of asserted claims, and has thus failed
to show that one skilled in art would have
been motivated to eliminate additional rare
earth elements and would have had reason-
able expectation of success in light of prior
art.

REMEDIES

5. Non-monetary and injunctive — Equita- ble relief — Preliminary injunctions — Patents (§505.0707.07)

Patent infringement plaintiff's showing of
likelihood of success on merits of infringe-
ment and validity issues warrants issuance of
preliminary injunction, since plaintiff's
showing on those issues is sufficiently strong
to invoke presumption of irreparable harm,
and since defendant has failed to rebut that
presumption.

6. Non-monetary and injunctive — Equita- ble relief — Preliminary injunctions — Patents (§505.0707.07)

Federal district court did not abuse its
discretion by finding that both balance of
hardships and public interest favor issuance
of injunction in action for infringement of
patent for solar control glass, since court has
not been unresponsive to defendant's interest
in meeting its current contract obligations,
or to public's interest in obtaining solar con-
trol glass.

Particular patents — Chemical — Solar control glass

5,240,886, Gulotta and Shelestak, ultravio-
let absorbing, green tinted glass, grant of

preliminary injunction in infringement suit
affirmed.

Appeal from the U.S. District Court for
the Western District of Pennsylvania, Lan-
caster, J.

Action by PPG Industries Inc. against
Guardian Industries Corp. for patent in-
fringement. From grant of plaintiff's motion
for preliminary injunction, defendant ap-
peals. Affirmed.

Arland T. Stein, Stanley D. Ference III, and
Cynthia E. Kernick, of Reed Smith Shaw
& McClay, and Mark Levin, of PPG In-
dustries Inc., Pittsburgh, Pa., for
plaintiff-appellee.

Daniel W. Vittum, Jr., and Jeffrey D. Mills,
of Kirkland & Ellis, Chicago, Ill., for
defendant-appellant.

Before Michel, Schall, and Bryson, circuit
judges.

Bryson, J.

This case concerns a dispute between two
major manufacturers of automotive glass;
the dispute revolves around glass composi-
tions known as "solar control glass," which
have the highly desirable characteristics of
filtering out most of the sun's ultraviolet and
infrared radiation while transmitting most of
the light in the visible part of the spectrum.
Appellee PPG Industries, Inc., which holds a
patent on a composition of solar control
glass, sued appellant Guardian Industries
Corporation for patent infringement and ob-
tained a preliminary injunction from the
United States District Court for the Western
District of Pennsylvania. The injunction pro-
hibits Guardian from making, using, or sell-
ing its own composition of solar control glass.
We conclude that the district court did not
abuse its discretion in granting preliminary
injunctive relief to PPG, and we therefore
affirm the order of the district court.

I

On August 31, 1993, the Patent and
Trademark Office issued U.S. Patent No.
5,240,886 (the '886 patent), which was as-
signed to PPG. Shortly after obtaining the
patent, PPG advised Guardian that it be-
lieved Guardian's solar control glass, known
as "Solar Management Glass" (SMG), in-
fringed PPG's rights under the patent. Liti-
gation followed, and after a five-day hearing

the district court granted PPG's motion for a preliminary injunction.

The district court found that PPG had established a likelihood of success on the merits by making a strong showing that SMG infringed PPG's rights under the patent and that the patent was not invalid. In light of PPG's showing on the merits, the court held that PPG was entitled to a presumption that it would suffer irreparable harm from Guardian's continued infringement. The court also found that the balance of hardships and the public interest weighed in favor of granting PPG's request for preliminary injunctive relief. Guardian brought this appeal, contesting the district court's ruling on each of those points.

II

A

The issue to which the parties devote the most attention is whether Guardian infringed claim 1 of the '886 patent and dependent claims 3 and 4. Claim 1 of the '886 patent defines a glass composition consisting of soda-lime-silica glass to which is added a set of ingredients that have the effect of selectively filtering out most of the sun's ultraviolet radiation. The filtering ingredients are identified in the claim as cerium (in the form of cerium oxide (CeO_2) and iron (in the ferric (Fe_2O_3) state). The claim requires that the composition have a total iron content of at least 0.85 percent by weight, and that the ratio of iron in the ferrous (FeO) state to total iron (known as the redox ratio) be no greater than 0.275. In full text, the claim reads as follows:

1. A green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of:

SiO_2	68-75 weight %
Na_2	10-20
CaO	5-15
MgO	0-5
Al_2O_3	0-5
K_2O	0-5

and a colorant portion consisting essentially of:

CeO_2	Less than 0.5 weight %
Total Iron	Greater than 0.85
(as Fe_2O_3)	weight %
$\text{FeO}/\text{total iron}$	Less than 0.275.

exhibiting ultraviolet transmittance no greater than 31 percent (300 to 390 nanometers) and luminous transmittance (illuminant A) of at least 70 percent, both at a reference thickness of 3.9 millimeters.

Dependent claim 3 adds the limitation that the dominant wavelength of the light transmitted by the glass must be between 495 and 535 nanometers (the green color range of the spectrum), and dependent claim 4 adds the requirement that the glass must exhibit a total solar energy transmittance (including ultraviolet, visible, and infrared radiation) of less than 45 percent at a reference thickness of 3.9 millimeters.

The ultraviolet and visible light transmission requirements set forth in the claims are those established by the automotive industry as the minimum standards for acceptable solar control glass. Prior to the '886 invention (and Guardian's SMG glass), solar control glass was often made with a significant amount of cerium, a rare earth element, in the form of cerium oxide. The principal benefit of the invention claimed in the '886 patent, as explained in the specification, is that it permits a manufacturer of solar control glass to meet industry standards while adding either no cerium or relatively little cerium to the glass. Minimizing the amount of cerium used in the glass is valuable because cerium is expensive and because it has the undesirable effect, after long-term exposure to ultraviolet radiation, of darkening the glass in which it is present.

The specification of the '886 patent contains a set of examples of compositions falling within the scope of claim 1 of the patent. The examples include several compositions containing relatively small amounts of cerium (between 0.27 and 0.31 percent cerium by weight) and one composition containing essentially no cerium. Each of the examples satisfies the transmittance requirements of the claim for visible light and ultraviolet radiation. The example that contains no cerium, however, shows a particularly low redox ratio. A low redox ratio, together with a relatively large amount of iron, has the effect of compensating for the absence of cerium in filtering out ultraviolet radiation. With respect to the no-cerium example, the specification further states that

the very low ferrous to total iron ratio required when no cerium is used may be difficult to attain in some melting furnaces. Therefore, it is preferred that a small amount of cerium be used to yield the desired reduction in ultraviolet transmittance without requiring an unduly low ferrous to total iron ratio.

While the '886 patent application was pending before the PTO, PPG obtained a sample of Guardian's SMG glass and tested it. When PPG's tests showed that the SMG sample did not meet the automobile manufacturers' standards for ultraviolet transmit-

the limitation that of the light trans- be between 495 and on color range of the at claim 4 adds the ass must exhibit a nittance (including frared radiation) of reference thickness

ible light transmis- in the claims are automotive industry rds for acceptable to the '886 inven- G glass), solar con- with a significant : earth element, in de. The principal claimed in the '886 he specification, is turer of solar con- y standards while or relatively little nizing the amount ss is valuable be- and because it has er long-term expo- n, of darkening the t.

e '886 patent con- compositions fall- im 1 of the patent. veral compositions l amounts of ceri- 31 percent cerium osition containing h of the examples e requirements of it and ultraviolet t contains no ceri- cularly low redox together with a iron, has the effect sence of cerium in diation. With re- mple, the specifi-

o total iron ratio n is used may be me melting fur- preferred that a be used to yield ultraviolet trans- ng an unduly low

o application was PPG obtained a glass and tested ed that the SMG automobile manu- aviolet transmit-

tançe, PPG advised Guardian of those re- sults. Guardian responded that under its tests SMG met the 31 percent ultraviolet transmittance requirement for the 300 to 390 nanometer range. When PPG re-exam- ined its testing procedures, it discovered that the software it was using in its testing equip- ment was flawed and that as a result the testing equipment had made an error in calculating not only the ultraviolet transmitt- ance of the SMG sample, but also the ultra- violet transmittance of each of the examples set forth in the '886 patent specification. Because of the software error, the ultraviolet transmittance reported in each example was about three percent too high; thus, the glass tested in each example was actually filtering out about three percent more ultraviolet ra- diation than the testing equipment indicated. That error had led the inventors to suggest in the specification that a glass meeting the limitations of the patent and containing no cerium at all might be difficult to make commercially, as it would require a redox ratio that would be hard to achieve in some commercial furnaces. In fact, however, the transmittance limitations of the claims for a no-cerium glass are not as difficult to satisfy as the specification suggests, because after an adjustment is made for the three percent calculation error, the redox ratio for the no-cerium embodiment does not have to be as low as the specification indicates.

Based on the three percent calculation error, Guardian argues that the claims of the '886 patent do not cover SMG. If the claims are read in light of the specification, Guard- ian argues, they cannot be construed to apply to SMG, because the examples in the specifi- cation make clear that the inventors did not believe that a glass having the composition of SMG would satisfy the 31 percent ultravio- let transmission requirement.

[1] The problem with Guardian's argu- ment is that the claims simply cannot be construed as Guardian suggests. By their plain terms, the claims read on SMG: the critical limitations require that the glass con- tain less than 0.5 percent cerium and more than 0.85 percent iron, that the redox ratio of the iron components be less than 0.275, that the ultraviolet transmittance be no greater than 31 percent, and that the visible light transmittance be at least 70 percent. SMG satisfies all of those limitations and thus infringes claim 1 of the '886 patent. More- over, because the dominant wavelength transmitted by SMG is within the green range (495 to 535 nanometers) and because SMG's total solar energy transmittance at the 3.9 millimeter reference thickness is less

than 45 percent, it falls within the limitations of dependent claims 3 and 4 as well.

It is true that if Guardian's SMG glass is tested with the same flawed testing equip- ment that was used to prepare the examples in the '886 patent specification, SMG's ul- traviolet transmittance would appear to be above the 31 percent maximum set forth in the claims. But the '886 patent claims are not qualified in that manner; the claims cover glass that transmits no more than 31 percent of the sun's ultraviolet radiation, not glass that is measured at no more than 31 percent ultraviolet transmittance with PPG's flawed testing system. Because it is undisput- ed that SMG transmits no more than 31 percent of the sun's ultraviolet radiation over the wavelength range of 300 to 390 nano- meters, and because that is the way the ultraviolet transmittance limitation is speci- fied in the patent claims, the claims cannot be construed in a way that renders SMG non-infringing.

B

In the alternative, Guardian argues that if the claims are interpreted to read on SMG, the patent is invalid under section 112 of the Patent Act, 35 U.S.C. § 112. Guardian makes three arguments in support of its section 112 claim. First, Guardian contends that the claims run afoul of the requirement of particularity and distinctness in para- graph 2 of section 112 because they fail to point out and distinctly claim what the inven- tors regarded as their invention. Second, Guardian argues that the claims violate paragraph 2 of section 112 for the additional reason that the inventors failed to state the method they used to measure the ultraviolet transmittance of the invention. Third, Guardian asserts that the patent is invalid because, in order for the claims to read on SMG, the claims must be interpreted as extending beyond the invention disclosed in the specification. In its reply brief, Guardian makes explicit that its third argument is based on the "enablement" requirement of paragraph 1 of section 112, not the "written description" requirement that appears in the same paragraph.

We reject each of the section 112 argu- ments on which Guardian relies. First, para- graph two of section 112 "is essentially a requirement for *precision and definiteness* of claim language." *In re Borkowski*, 422 F.2d 904, 909, 164 USPQ 642, 646 (CCPA 1970) (emphasis in original); the "requirement is that the language of the claims must make it clear what subject matter they encompass,"

In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970).

[2] There is nothing imprecise or indefinite about the claim language in the '886 patent. The claims are quite precise in quantifying the essential ingredients and transmittance tolerances of the claimed compositions: on their face, the claims give clear notice of what compositions fall within their scope. Because the claims "reasonably apprise those skilled in the art both of the utilization and scope of the invention," and because "the language is as precise as the subject matter permits," *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (internal quotation omitted), *cert. dismissed*, 474 U.S. 976 (1985), the claims are not invalid for indefiniteness.

Guardian argues that the patent nonetheless violates paragraph 2 of section 112 because the inventors would not have believed at the time of their application that glass having the composition of SMG could meet the transmittance limitations of the claims. That misconception on the part of the inventors, however, does not mean that they failed to "distinctly claim[] the subject matter which [they] regard[ed] as [their] invention." 35 U.S.C. § 112, ¶2. The inventors regarded their invention as a glass containing filtering ingredients within the defined composition ranges and producing an ultraviolet transmittance of no more than 31 percent and a visible light transmittance of at least 70 percent, and that is what they claimed. Guardian relies on cases in which the claims included "a substantial measure of inoperatives," *In re Corkill*, 771 F.2d 1496, 1501, 226 USPQ 1005, 1009 (Fed. Cir. 1985), or cases in which "some material submitted by applicant, other than his specification, shows that a claim does not correspond in scope with what he regards as his invention," *In re Conley*, 490 F.2d 972, 976, 180 USPQ 454, 457 (CCPA 1974) (emphasis in original; citing *In re Cormany*, 476 F.2d 998, 177 USPQ 450 (CCPA 1973), and *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1973)). In this case, by contrast, the claims were written in a manner that required all the embodiments to be operative; the claims set out exactly what the inventors intended to claim as their invention; and Guardian does not point to any statement by the applicants outside the specification that indicates that they did not intend to claim all species having the recited limitations. Moreover, nothing in the specification renders any of the claim language ambiguous, such that a person skilled in the art would be uncertain about "what subject matter falls within the

scope of the claims." *In re Miller*, 441 F.2d 689, 692, 169 USPQ 597, 599 (CCPA 1971); see *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). There is therefore no force to Guardian's argument that the claims did not accurately and distinctly set out what the inventors regarded as their invention.

Second, the patent is not rendered invalid on the ground that the inventors failed to specify the method to be used in measuring the ultraviolet transmittance set forth in the claims. The evidence at the preliminary injunction hearing established that, setting aside the equipment error that plagued PPG's testing procedures, all of the conventional methods of testing ultraviolet transmittance produce essentially identical results. Accordingly, the claim limitation of no more than 31 percent ultraviolet transmittance, in conjunction with the other limitations, is sufficiently definite to put the public on fair notice of what compositions fall within the scope of the claims. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

Third, the specification satisfies the enablement requirement of section 112, paragraph 1, which requires that the specification contain a description "of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112, ¶1. The specification of the '886 patent describes in ample detail how to make and use the invention with respect to the seven specific embodiments set forth in the experimental examples. And Guardian does not dispute that the specification enables all embodiments falling within the other claim limitations and having an ultraviolet transmittance of 28 percent or less (which is the transmittance that PPG's flawed testing equipment reported as 31 percent). The only contested issue is whether the '886 patent must be held invalid on the ground that the specification fails to satisfy the enablement requirement with respect to embodiments having an actual ultraviolet transmittance of less than 31 percent, but which PPG's equipment would have reported as more than 31 percent.

In pressing its enablement argument, Guardian focuses on the portion of the specification that suggests a particularly low redox ratio is necessary to satisfy the ultraviolet transmittance limitation if the patented invention is made without any cerium. The test results and the statement on which

re Miller, 441 F.2d 597, 599 (CCPA 39 F.2d 1232, 1235, (PA 1971)). There is guardian's argument accurately and dis-inventors regarded as

not rendered invalid inventors failed to used in measuring once set forth in the preliminary inished that, setting error that plagued all of the conven- ultraviolet trans- tially identical re- m limitation of no ultraviolet trans- h the other limita- te to put the public positions fall with- ns. See *Hybritech, ibodies, Inc.*, 802 PQ 81, 94-95 (Fed. d, 480 U.S. 947

satisfies the enab- section 112, para- that the specifica- n "of the manner d using [the inven- concise, and exact person skilled in the to make and use 12, ¶1. The speci- describes in ample use the invention a specific embodi- experimental exam- not dispute that the bodiments falling tations and having ce of 28 percent or tance that PPG's reported as 31 per- ssue is whether the ld invalid on the ion fails to satisfy nt with respect to actual ultraviolet a 31 percent, but ould have reported

ement argument, ortion of the speci- rticularly low re- tisfy the ultravio- n if the patented any cerium. The ement on which

Guardian relies are products of PPG's software error; the effect of the error was to make the ultraviolet transmittance figures appear artificially high and thus to make it appear that in order to attain the 31 percent ultraviolet transmittance limitation in the claims, the composition would need more iron and a lower redox ratio, both of which have the effect of reducing ultraviolet transmittance.

[3] We are not persuaded that the calculation error and the statements in the specification regarding the need for a low redox ratio in a no-cerium embodiment of the invention give rise to a violation of the enablement requirement. It is true that, in order to be enabling, a specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 495-96, 20 USPQ2d 1438, 1444-45 (Fed. Cir. 1991). Moreover, Guardian is correct that a careful reader of the specification could well conclude that a glass with the iron content and redox ratio of SMG would not be likely to satisfy the ultraviolet transmittance limitation of the claims. The district court found, however, that PPG's calculation error was "harmless, inconsequential, and easily detectable by anyone who was skilled in the art of processing solar controlled glass." We interpret that statement as a factual finding that PPG's error could be discovered without "undue experimentation" by a person having ordinary skill in the art, and thus that the enablement requirement of section 112 was satisfied. See *In re Vaeck*, 947 F.2d at 495, 20 USPQ2d at 1444 ("Enablement . . . is a question of law which we independently review, although based upon underlying factual findings which we review for clear error.").

In light of the district court's finding, we cannot agree with Guardian that the specification of the '886 patent does not "teach those skilled in the art how to make and use the full scope of the claimed invention." *In re Wright*, 999 F.2d at 1561; 27 USPQ2d at 1513. In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., *In re Goodman*, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed.

Cir.), *cert. denied*, 502 U.S. 856 (1991); *In re Vaeck*, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

In this case, the district court was justified in finding that undue experimentation would not be required to make an embodiment of the '886 patent having the same composition and transmittance properties as SMG. One of the examples in the specification describes a glass containing no cerium, but having a lower redox ratio and a higher iron content than SMG. The specification teaches that as the iron content of the glass is reduced and the redox ratio rises, the glass transmits more ultraviolet radiation. A person reading the specification could therefore start with the no-cerium example and make a glass similar to SMG by simply lowering the iron content and allowing the redox ratio to rise until the ultraviolet transmittance reached the 31 percent limitation.

Another example given in the specification has roughly the same composition as SMG except that it contains a small amount of cerium. Following the principles taught in the specification, an experimenter could produce an embodiment of the '886 patent with a composition and properties similar to SMG simply by keeping the iron content and the redox ratio fixed, and reducing the cerium content to zero. In preparing that embodiment, the experimenter would discover that the ultraviolet transmittance calculations for the examples found in the patent specification are a few percent too high, but that error would not affect the experimenter's ability to make the desired embodiment.

Where the specification provides "guidance in selecting the operating parameters that would yield the claimed result," *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring) (emphasis omitted), it is fair to conclude that the experimentation required to make a particular embodiment is not "undue." Although PPG's software error made it appear that commercial production of a no-cerium composition that satisfied the transmittance limitations would be difficult, the specification made it clear that such a composition could be made, and it indicated to one skilled in the art how to maintain low ultraviolet transmittance while minimizing the cerium content of the glass. Thus, the specification gave "considerable direction and guidance on how to practice [the] invention." *In re Wands*, 858 F.2d 731, 740, 8 USPQ2d 1400, 1406 (Fed. Cir. 1988).

In light of the guidance provided by the specification, this case is quite different from those in which enablement has been found lacking because of the need for "undue experimentation." See, e.g., *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 790-92, 218 USPQ 961, 962-64 (Fed. Cir. 1983) (a requirement of 18 months to two years' work to practice the patented invention is "undue experimentation"); *In re Ghiron*, 442 F.2d 985, 992, 169 USPQ 723, 727-28 (CCPA 1971) (a development period of "many months or years ... does not bespeak a routine operation but of extensive experimentation and development work"). It was therefore reasonable for the district court to conclude that the patent was not invalid for lack of enablement.

C
Guardian next contends that it does not infringe PPG's rights under the '886 patent, because SMG contains a sulfur compound that significantly affects its filtering properties, and the claims of the '886 patent therefore do not read on SMG glass. The district court acknowledged that SMG contains sulfur, but it found that the sulfur contained in SMG has no material effect on the filtering properties of the glass.

Guardian contends that the district court committed clear error in the factual finding it made on the sulfur issue. The court's finding, however, was based on an extensive exploration of the issue through testimony and documents at the five-day preliminary injunction hearing. Although Guardian introduced documentary evidence that sulfur

can affect the transmittance properties of glass, Guardian did not persuade the district court — and has not persuaded us — that those authorities prove that sulfur has such an effect when the redox ratio is as low as it is in Guardian's accused SMG product.

Guardian challenges the testimony of PPG's expert on the sulfur issue, but the court heard testimony by experts from both sides and found PPG's expert testimony more convincing. Because we do not find PPG's presentation on the sulfur issue inherently implausible, we are satisfied that the district court's finding on that issue is not clearly erroneous.

D

Guardian's next argument is that PPG failed to satisfy its burden of showing that the '886 patent is likely to survive challenges based on Guardian's defenses of anticipation and obviousness. Before the district court, Guardian argued that example 4 in Russian Patent No. 948,912 anticipated, or at least rendered obvious, claim 1 of the '886 patent. Guardian urges that in rejecting its contention, the district court applied an erroneous legal standard and did not make sufficiently detailed factual findings to permit meaningful review by this court.

The district court concluded that there was no factual basis to support a finding of invalidity, because the Russian patent teaches that significant amounts of cerium and other rare earth elements that absorb ultraviolet light are necessary to reduce ultraviolet transmission to the level set forth in claim 1 of the '886 patent. To be sure, the district court did not articulate the correct legal standard when it stated that to invalidate a patent the prior reference must "give the same knowledge and the same directions" as the challenged patent. The ultimate question, however, is whether the challenger's evidence of invalidity is sufficiently persuasive that it is likely to overcome the presumption of patent validity. See *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 USPQ2d 1622, 1625 (Fed. Cir. 1992). In view of the limited record presented to the district court on this issue, we agree with the court's conclusion that Guardian's argument based on the Russian patent failed to "raise[] a substantial question" of invalidity. *Id.*

[4] To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. *Chester v. Miller*, 906 F.2d 1574, 1576 n.2, 15

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cluded that there support a finding of ssian patent teach- ts of cerium and that absorb ultra- to reduce ultravio- l set forth in claim e sure, the district the correct legal at to invalidate a e must "give the ame directions" as he ultimate ques- the challenger's ufficiently persua- come the presump- ee *New England erterton Co.*, 970 1622, 1625 (Fed. he limited record- ourt on this issue, s conclusion that d on the Russian- substantial ques-

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USPQ2d 1333, 1336 n.2 (Fed. Cir. 1990); *In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985). Guardian has not shown that the composition described in example 4 of the Russian patent meets the limitations of the claim, because that composition contains significant amounts of several rare earth elements that absorb ultraviolet radiation as well as visible light.

In presenting its defense of obviousness, Guardian again relied principally on the Russian patent. In the district court, however, Guardian did not demonstrate that the claimed invention would have been obvious to one skilled in the art in light of the disclosures in that reference. In its presentation to us, moreover, Guardian has not pointed to any evidence showing that the district court's factual finding that the Russian patent teaches away is clearly erroneous. Therefore, Guardian has failed to provide any basis for concluding that one skilled in the art would have been motivated to eliminate the additional rare earth elements recited in example 4 of the Russian patent and would have had a reasonable expectation of success in light of the prior art. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). For purposes of the preliminary injunction proceedings, PPG has thus satisfied its burden of showing a likelihood of success on the validity issue.

E

Guardian also challenges the district court's conclusion that PPG would suffer irreparable harm if preliminary injunctive relief were not granted. Because the district court found that PPG had made a clear showing that it was likely to prevail on the issues of patent validity and infringement, the court held that PPG was entitled to a presumption of irreparable harm. See *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390, 2 USPQ2d 1926, 1930 (Fed. Cir. 1987); *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230, 1233, 227 USPQ 289, 292 (Fed. Cir. 1985). In addition, the district court found that in the absence of injunctive relief PPG's significant position in the solar control glass market would be threatened.

[5] Guardian places heavy reliance on this court's decision in *High Tech Medical Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 33 USPQ2d 2005 (Fed. Cir. 1995), where the court reversed a preliminary injunction in part because of an inadequate showing of irreparable harm. In

that case, however, the court concluded that the patentee was unlikely to succeed on the merits of its infringement claim and therefore held that the presumption of irreparable harm was inapplicable. 49 F.3d at 1556, 33 USPQ2d at 2009. In this case, by contrast, we have upheld the district court's conclusion that PPG is likely to succeed at the merits stage on the issues of infringement and validity, and we agree that PPG's showing on those issues was sufficiently strong to invoke the presumption of irreparable harm. Because we agree with the district court that Guardian failed to rebut that presumption, we sustain the court's ruling that PPG met its burden of showing that it would suffer irreparable harm in the absence of an order granting preliminary injunctive relief.

F

Finally, Guardian argues that the balance of hardships and the public interest both counsel in favor of denying the injunction. The district court, however, considered both factors and reached the contrary conclusion, and we are not prepared to overturn that determination. The district court concluded that PPG would suffer significant harm from the denial of an injunction, while an injunction would be less burdensome for Guardian, as it would require only a temporary interruption in Guardian's production and sale of its SMG glass. With regard to the public interest, the court acknowledged that an injunction would deprive the public of one of the suppliers of solar control glass. The court, however, balanced that interest against the strong public policy favoring the enforcement of patent rights. Because the court found it unlikely that the injunction would result in a shortage of solar control glass, the court found that, on balance, the public interest favored PPG.

[6] Guardian argues that PPG will be unable to satisfy the requirements of Guardian's customers, particularly the large automobile manufacturers, for solar control glass. To address that objection, however, the district court gave Guardian the right to return to court for relief from the preliminary injunction if Guardian were unable to fulfill its current contracts with automobile manufacturers, either with noninfringing compositions or by purchase from PPG on reasonable terms. Guardian made an initial request for temporary relief from the injunction, which was granted. The record does not reflect that Guardian has made any further requests, although the district court has made clear that it would be prepared to entertain any such requests if they should be

made. In the absence of a showing that the district court has been unresponsive to Guardian's interest in fulfilling its current contract obligations, or to the public's interest in obtaining an adequate supply of solar control glass, we cannot conclude that the district court abused its discretion in finding that both the balance of hardships and the public interest favor PPG.

III

The unusual circumstances surrounding the prosecution of the '886 patent have made this preliminary injunction proceeding difficult. Nonetheless, we have carefully reviewed each of the numerous legal points that Guardian has raised in challenging the injunction, and we conclude that none of them requires that we upset the district court's order. Guardian will have an opportunity at the merits stage to present and expand upon the arguments it has made at the preliminary injunction stage, as well as any additional arguments that it chooses to present, and the district court will be able to give those arguments plenary consideration at that time. The record as it now stands, however, compels us to conclude that the district court did not abuse its discretion in granting the preliminary injunction.

AFFIRMED.

U.S. Court of Appeals Federal Circuit

Pro-Mold and Tool Co. v. Great Lakes
Plastics Inc.

Nos. 95-1171, -1181

Decided February 7, 1996

PATENTS

1. Patentability/Validity — Obviousness — Relevant prior art — Particular inven- tions (§115.0903.03)

Patentability/Validity — Obviousness — Combining references (§115.0905)

Two holders for sports trading cards, viewed together, provide all elements in asserted claim of allegedly infringed patent for card holder, since one card holder includes all elements of invention except for size, and since second card holder, which is only slightly larger than stored trading card, provides size element; second card holder is

prior art to patent in suit, since it was advertised in 1988, 1989, and 1990.

2. Patentability/Validity — Obviousness — Combining references (§115.0905)

Reason, suggestion, or motivation to combine two or more prior art references in single invention may come from references themselves, from knowledge of those skilled in art that certain references or disclosures in references are known to be of interest in particular field, or from nature of problem to be solved; in present case, motivation to combine friction-fit cover of one prior art sports trading card holder with small size of second card holder arose from size of trading cards themselves, since card holder that is substantially same size as trading card, and that would therefore be of proper size to fit within conventional storage set box, was clearly desirable.

3. Patentability/Validity — Obviousness — Commercial success (§115.0908)

Federal district court erred by granting summary judgment that plaintiff's patent for sports trading card holder is obvious, since plaintiff presented evidence that it sold approximately 3.2 million card holders in one year, since plaintiff's lack of previous experience in relevant market, combined with high sales of patented product, provides inference of nexus between commercial success and features of patented invention, since plaintiff's evidence of commercial success created genuine issues of material fact on question of obviousness, and since district court did not provide reasons for apparently discounting plaintiff's evidence of secondary considerations.

JUDICIAL PRACTICE AND PROCEDURE

4. Procedure — Court of Appeals for the Federal Circuit (§410.03)

Court of Appeals for the Federal Circuit will not defer to regional circuit law on issue of whether alleged inequitable conduct in prosecution of patent application constitutes unfair competition, since issue clearly impacts Federal Circuit's exclusive jurisdiction.

TRADEMARKS AND UNFAIR TRADE PRACTICES

5. Unfair competition — Other federal stat- utes (§395.06)

Patent infringement defendant's assertion that plaintiff acted in bad faith by filing infringement complaint knowing that patent was unenforceable does not establish claim

titled to summary judgment on the 1202(b)(3) claim.

A section 1202(b)(1) violation occurs when a person (i) without authority of the copyright owner or the law (ii) intentionally removes or alters any copyright management information (iii) knowing or having reasonable grounds to know that it will induce, enable, facilitate, or conceal an infringement of the federal copyright laws. Although Gordon failed to introduce evidence that Nextel or Mullen was aware of any infringement until they received the cease and desist letter from Gordon's counsel, he argues that because the copyright information is absent from the illustrations, Crossroads must have removed it, and that Nextel and Mullen are liable for Crossroads' actions.

The defendants assert several defenses to Gordon's 1202 claim. First, they assert that Gordon failed to present any evidence that Nextel or Mullen's conduct brings them within any of the elements set forth in section 1202. However, as outlined above, the defendants may be vicariously liable for the actions of Crossroads and its employees.

Defendants next claim that here, as in *Kelly v. Ariba Soft Corp.*, there is no proof that the copyright information was removed from the individual illustrations, rather than the white space surrounding the illustrations themselves. However, the parties dispute whether the posters used in the advertisement were made from Gordon's wallchart or the booklet, which contained the copyright management information within the individual illustrations. Because this clearly is a dispute of material fact, it is not appropriate to grant summary judgment on this basis.

Next, the defendants assert that, even if they are vicariously liable for the actions of Crossroads, there is no proof that any removal by Crossroads was intentional. In support, they point to the testimony of Kevin McCarthy, who stated that no one at Crossroads intended to or did remove the copyright notice from the artwork. McCarthy admits that he used the rental poster, scanned and enlarged a portion of it, and made the framed pictures that were used as the set decorations. McCarthy admits that he removed the information, and there is no suggestion that the removal was unintentional.

[4] Defendants further contend that Gordon submitted no proof that the removal of the

copyright notice was done with the requisite "reason to know that the removal would induce, enable, facilitate, or conceal an infringement." 17 U.S.C. § 1202(b). Rather, when Crossroads obtained the poster from the prop company, its personnel believed that the poster had been cleared for use in television commercials. As a result, the defendants assert, there is no evidence that Crossroads had any reason to know that the removal would facilitate or conceal an infringement. Furthermore, McCarthy asserts that it was his practice to obtain permission from an artist if the artwork was not obtained from a prop house, and that he would have sought Gordon's approval if he thought there was a clearance issue in this case. The record contains no evidence to counter McCarthy's testimony. As a result, Gordon may not claim that the copyright information was removed with reasonable grounds to know that it would "induce, enable, facilitate, or conceal an infringement." See 1202(b). We believe that the district court correctly granted summary judgment for the defendants on Gordon's 1202 claims.

For the foregoing reasons, we affirm the district court's opinion in its entirety.

**Elan Pharmaceuticals Inc. v. Mayo
Foundation for Medical Education and
Research**

**U.S. Court of Appeals
Federal Circuit**

No. 00-1467

Decided October 2, 2003

PATENTS

**[1] Patentability/Validity — Anticipation
— Prior art (§ 115.0703)**

**Patentability/Validity — Specification —
Enablement (§ 115.1105)**

Disclosure of assertedly anticipating prior art reference must be adequate to enable possession of desired subject matter, and reference that names or describes desired subject matter thus does not anticipate if subject matter cannot be produced without undue experimentation; in present case, summary judgment

that patents for transgenic animals harboring amyloid precursor protein allele having "Swedish mutation" are anticipated by prior art reference must be vacated and remanded for determination of whether reference enabled persons of ordinary skill in field of invention to make desired transgenic mouse without undue experimentation, since federal district court did not directly address question of enablement, which was not subject of summary judgment motion.

Particular patents — Chemical — Transgenic animals

5,612,486, McConlogue and Zhao, transgenic animals harboring APP allele having Swedish mutation, summary judgment of invalidity reversed.

5,850,003, McConlogue and Zhao, transgenic rodents harboring APP allele having Swedish mutation, summary judgment of invalidity reversed.

Appeal from the U.S. District Court for the Northern District of California, Alsup, J.

Action by Elan Pharmaceuticals Inc. and Athena Neurosciences Inc. against Mayo Foundation for Medical Education and Research for patent infringement. Plaintiffs appealed from summary judgment holding patents in suit invalid for anticipation. Initial opinion on appeal (64 USPQ2d 1292) was vacated, and is replaced with present opinion. Summary judgment of invalidity reversed and remanded.

Lynn H. Pasahow and Charlene M. Morrow, of Fenwick & West, Mountain View, Calif.; Beth H. Parker, Mary T. Huser, and S. Christian Platt, of Bingham McCutchen, Palo Alto, Calif.; Thomas S. Hixson, of Bingham McCutchen, San Francisco, Calif., for plaintiffs-appellants.

Robert E. Hillman, of Fish & Richardson, Boston, Mass.; Shelley K. Wessels, Karen I. Boyd, and Kurtis D. MacFerrin, of Fish & Richardson, Menlo Park, Calif.; Chad A. Hanson, of Fish & Richardson, Minneapolis, Minn., for defendant-appellee.

Before Newman, Gajarsa, and Dyk, circuit judges.

Newman, J.

The initial opinion in this appeal, reported at *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 304 F.3d 1221, 64 USPQ2d 1292 (Fed. Cir. 2002), has been vacated, 314 F.3d 1299 (Fed. Cir. 2002) (*en banc*) and is replaced with this opinion and decision.

The United States District Court for the Northern District of California, granting the Mayo Foundation's motion for summary judgment of patent invalidity, held that Elan's two patents in suit, United States Patent No. 5,612,486 (the '486 patent) for "Transgenic Animals Harboring APP Allele Having Swedish Mutation," and Patent No. 5,850,003 (the '003 patent) for "Transgenic Rodents Harboring APP Allele Having Swedish Mutation," are invalid on the ground of anticipation by United States Patent No. 5,455,169 entitled "Nucleic Acids for Diagnosing and Modeling Alzheimer's Disease" (the Mullan reference).¹

In response to the questions raised in the petitions for reconsideration, we clarify that invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation. Applying this rule, we remand for determination of whether the Mullan reference was an enabling disclosure. The summary judgment is reversed, and the case is remanded for further proceedings.

BACKGROUND

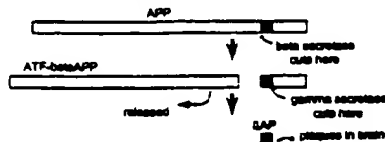
At the time of the Elan invention it was known that the brains of people with Alzheimer's disease contain abnormal tangles and deposits of plaques, and that a principal component of the plaques is a protein fragment called beta-amyloid peptide or betaAP (also designated β AP and A β). The formation of betaAP in brain tissue is believed to induce or foster formation of Alzheimer's disease plaques.

It is believed that a mechanism by which betaAP is formed is the abnormal cleavage of a protein produced in brain cells, called the amyloid precursor protein (APP); and that this abnormal cleavage occurs when an enzyme produced in the brain, called beta-secretase, cleaves the APP molecule between amino acids 596 and 597; and a second enzyme pro-

¹ *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research*, 175 F.Supp.2d 1209 (N.D. Cal. 2000).

duced in the brain, called gamma-secretase, releases the betaAP fragment from a portion of the cleaved APP. The mechanism is illustrated in the Elan brief as follows:

Fig.1 - Processing of APP to β AP and ATF-betaAPP



Humans who do not develop Alzheimer's disease are believed to break down the APP in a manner that does not form significant amounts of betaAP in the brain.

The Swedish mutation is an abnormal gene² that was discovered on chromosome 21 in a Swedish family that has an unusually high incidence of early-onset Alzheimer's disease. This mutation is described in the Mullan patent as a variation in the DNA nucleotides that encode codons 670 and 671,³ wherein lysine and methionine, the amino acids normally encoded at these positions, are replaced with asparagine and leucine.

The Elan patents are directed to transgenic rodents whose genetic makeup has been modified to include the Swedish mutation. Claim 1 of the '486 patent is representative:

1. A transgenic rodent comprising

a diploid genome comprising a transgene encoding a heterologous APP polypeptide having the Swedish mutation wherein the amino acid residues at positions corresponding to positions 595 and 596 in human APP695 are asparagine and leucine, respectively,

wherein the transgene is expressed to produce a human APP polypeptide having the Swedish mutation,

and wherein said polypeptide is processed to ATF-betaAPP in a sufficient

amount to be detectable in a brain homogenate of said transgenic rodent.

Dependent claims add the limitations that the rodent is murine (mouse) and that the transgene is nonhomologously integrated.

The claims of the '003 patent differ only in that they include a promoter and a polyadenylation site. Claim 1 is representative:

1. A transgenic rodent comprising

a diploid genome comprising a transgene comprising in operable linkage a promoter, a DNA segment encoding a heterologous APP polypeptide and a polyadenylation site,

wherein the APP polypeptide has the Swedish mutation whereby the amino acid residues at positions corresponding to positions 595 and 596 in human APP695 are asparagine and leucine, respectively,

wherein the transgene is expressed to produce a human APP polypeptide having the Swedish mutation,

and wherein said polypeptide is processed to ATF-betaAPP in a sufficient amount to be detectable in a brain homogenate of said transgenic rodent.

The Mullan reference was cited as prior art in prosecution of the Elan patents, and was distinguished upon amendment of the Elan claims to include the claim clause that refers to production of ATF-betaAPP in detectable amounts in the rodent brain.

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The district court, granting Mayo's motion for summary judgment, held that the Mullan reference anticipates the Elan invention. Whether an invention is anticipated is a question of fact. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995). On appeal, Elan requests review of the district court's determination that the Mullan reference anticipates the claims of the Elan patent because the Elan mouse is inherent in Mullan. We conclude that Elan's arguments are more properly characterized as enablement arguments rather than inherency arguments.

To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art

² A gene is a segment of DNA that encodes for and leads to the production, through several complex steps, of the sequence of amino acids that constitutes a protein. A mutation is a change in the gene DNA and the changes in the ensuing products. See Bruce Alberts et al., *Essential Cell Biology* (1998), Ch.6 "DNA," Ch.7 "From DNA to Protein."

³ The positions at codons 670/671 (Mullan) and codons 596/597 (Elan) are the same, due to differing starting points in the APP chain. See '486 patent, col. 11, lines 29-34.

are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See *Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipated subject matter."). Review of Elan's opposition to Mayo's motion for summary judgment shows that, while Elan purports to contest Mayo's motion on the grounds that the Mullan patent does not inherently anticipate the Elan claimed mouse, the language and factual basis of this argument encompass enablement.

Enablement requires that "the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation." *Minnesota Mining and Manufacturing Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301, 64 USPQ2d 1270, 1278 (Fed. Cir. 2002); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369, 52 USPQ2d 1129, 1134 (Fed. Cir. 1999) ("Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1, is a question of law that we review de novo, based on underlying factual inquiries that we review for clear error.").

The factual premises of the enablement analysis for biological processes were addressed in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court explaining that determination of whether the requisite amount of experimentation is undue may include consideration of:

- (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737; 8 USPQ2d at 1404. See *Amgen, Inc. v. Chugai Pharm. Co.*, 727 F.2d 1200,

1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (discussing application of the *Wands* factors). In *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) the *Wands* factors were applied to a gene transformation method, the court finding that the method "would have required extensive experimentation that would preclude patentability."

[1] The disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter. It is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation. The principles underlying application of the criteria of enablement to the content of the prior art were discussed in *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985):

It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.

Id. at 533, 226 USPQ at 621. See also *In re Borst*, 345 F.2d 851, 855, 145 USPQ 554, 557 (CCPA 1962) ("the disclosure must be such as will give possession of the invention to the person of ordinary skill. Even the act of publication or the fiction of constructive reduction to practice will not suffice if the disclosure does not meet this standard.").

The determination of what level of experimentation is "undue," so as to render a disclosure non-enabling, is made from the viewpoint of persons experienced in the field of the invention. See *Enzo Biochem*, 188 F.3d at 1373-74 (discussing evidence of enablement and nonenablement in an unpredictable field of biotechnology). "The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art." *In re Wands*, 858 F.2d 731, 737 [8

USPQ2d 1400] (Fed. Cir. 1988). In *Wands* the court observed that "[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed" *Id.*, quoting *In re Jackson*, 217 USPQ 804, 817 (Bd. App. 1982).

The Mullan reference contains an extensive description of the Swedish mutated gene, its source, the nature of the mutation, and its role in Alzheimer's disease. The reference also states that the invention provides a transgenic animal whose cells contain the mutated gene and express the Swedish mutated protein:

The invention also provides a transgenic non-human animal containing, in a germ or somatic cell, the mutated nucleic acid of the invention, wherein the animal expresses a human amyloid precursor protein or fragment thereof which encodes an amino acid other than lysine at codon 670 and/or an amino acid other than methionine at codon 671.

Mullan, col. 4, lines 35-40. Elan argues that the Mullan reference does not show all of the limitations of the Elan claims and does not enable the transgenic animal it describes. Elan stresses the uncertainty and difficulty of producing a transgenic animal, and argues that although Mullan foresaw a transgenic mouse and presented a compilation of known methods of gene transfer, the reference does not teach or suggest which method might succeed in creating the desired mutated mouse. Mayo in turn stresses the comprehensiveness of the Mullan disclosure, and that Elan indeed eventually succeeded with one of the methods mentioned by Mullan, using the Swedish gene discovered by Mullan and a mouse species recited by Mullan.

The Mullan reference summarizes the various known gene transfer techniques, with citations to scientific literature describing these techniques. The following extract is illustrative:

One approach to creating transgenic animals is to target a mutation to the desired gene by homologous recombination in an embryonic stem (ES) cell line in vitro followed by microinjection of the modified ES cell line into a host blastocyst and subse-

quent incubation in a foster mother (see Frohman and Martin, *Cell* (1989) 56:145). Alternatively, the technique of microinjection of the mutated gene, or a portion thereof, into a one-cell embryo followed by incubation in a foster mother can be used. Certain possibilities for the general use of transgenic animals, particularly transgenic animals that express a wildtype APP fragment, are disclosed in Wirak et al., the *EMBO Journal*, 10(2) 289296 (1991); Schilling et al., *Gene* 98(2) 225230 (1991); Quon, et al. (1991) *Nature* 352:239; Wirak, et al. (1991) *Science* 253:323; and Kawabata, et al. (1991) *Nature* 354:476. Alternatively, viral vectors, e.g., Adenoassociated virus, can be used to deliver the mutated gene to the stem cell. In addition, such viral vectors can be used to deliver the mutated gene to a developed animal and then used to screen (Mendelson et al., *Virology* 166:154165; Wondisford et al. (1988) *Molec. Endocrinol.* 2:3239 (1988)).

Mullan, col. 11, line 58 to col. 12, line 11. Mullan states that site-directed mutagenesis can also be used, preferably so as to produce the desired mutation. The Mullan reference also names various known cloning vectors for creation of transgenic animals, and states that the vector is "selected based on the size of the desired insert and the ability to produce stable chromosome integration." The Mullan reference contains additional information, with citations to scientific articles and textbooks, proposing how vectors "can be constructed," the transgene "can be injected," and like statements.

Elan stresses that Mullan does not suggest which, if any, of the methods and vectors he cites might reasonably be predicted to succeed in producing a mouse operatively harboring the Swedish mutation. As explained in *Enzo Biochem*, 188 F.3d at 1372, "an enablement determination is made retrospectively, i.e., by looking back to the filing date of the patent application and determining whether undue experimentation would have been required to make and use the claimed invention at that time." Thus the enablement of the Mullan and Elan mice would be determined separately.

The issue is not whether the Mullan teachings are an accurate compilation of the state of the scientific art at that time, and they are not challenged on that ground. The issue is whether his teachings enabled a person of or-

inary skill, without undue experimentation, to produce the desired transgenic mouse. The district court did not directly address the question of enablement, which was not the subject of the summary judgment motion.

Thus we remand for determination by the district court, upon consideration of relevant evidence and upon application of the law to the facts of this case, of whether the Mullan reference enabled persons of ordinary skill in the field of the invention to make the desired mutated mouse without undue experimentation.

II

This appeal was directed to the summary judgment that was granted on the ground of anticipation. Mayo's other defenses of invalidity, and the question of infringement, were not reached by the district court. Mayo's argument that the claims are invalid under § 103 and/or § 112, particularly if construed to have the breadth that Elan ascribes to them in order to reach the Mayo mouse, and any other issues properly raised, remain for consideration on remand.

REVERSED AND REMANDED

Bretford Manufacturing Inc. v. Smith System Manufacturing Co.

U.S. District Court
Northern District of Illinois

No. 98 C 0287

Decided October 6, 2003

TRADEMARKS AND UNFAIR TRADE PRACTICES

[1] Infringement; conflicts between marks — Passing off (§ 335.07)

Defendant did not engage in reverse passing off or false advertising in violation of Lanham Act's Section 43(a), 15 U.S.C. § 1125(a), by using table leg manufactured by plaintiff as part of table defendant submitted to school district as sample, since "goods" offered for sale by defendant were tables later purchased by school district after it awarded contract to defendant, not sample table, since there was no misrepresentation by defendant as to "ori-

gin" of those tables, in that there was no misrepresentation, express or implied, as to source of components of those tables, since, even if sample table were considered "good" sold by defendant, there was no misrepresentation as to "origin" of sample, in that purchaser was not concerned with source of component parts, and since defendant had no duty to inform school district where it had obtained components used to assemble sample table; thus, component parts are not material to plaintiff's claims, and there was no misrepresentation or false advertising in regard to completed products.

Action by Bretford Manufacturing Inc. against Smith System Manufacturing Co. for violation of Lanham Act's Section 43(a), 15 U.S.C. § 1125(a). On defendant's motion for reconsideration of district court's ruling that defendant engaged in reverse passing off in violation of Section 43(a). Granted; prior ruling vacated.

Bart A. Lazer and Theodore Koerth, of Seyfarth Shaw, Chicago, Ill., for plaintiff.

Thomas J. Wimbiscus, Alejandro Menchaca, and Dennis P. Hackert, of McAndrews, Held & Malloy, Chicago, for defendant.

Grady, J.

ORDER

On June 5, 2001, after an evidentiary hearing, we ruled that the defendant, Smith System Manufacturing Company, had engaged in "reverse passing off" in violation of § 43(a) of the Lanham Act when it used a leg from a table manufactured by the plaintiff, Bretford Manufacturing, Inc., as part of a table it submitted to the Dallas Independent School District ("District") as a sample. Smith's bid was accepted by the School District on the basis of the sample, and we later held that in these circumstances Bretford was entitled to recover from Smith the profits that Smith realized on its contract with the District. Most recently, we have had under advisement the motion of Bretford for attorneys' fees and Smith's objections to that motion.

Now there is a new development. On July 21, 2003, Smith filed a motion for reconsideration of our ruling that its use of the Bretford leg in the sample constituted reverse

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